

REMARKS

Upon entry of this Response, the subject application will contain claims 72-135 pending and under consideration. Claims 72-134 were rejected under 13 USC §112, first paragraph, and claims 72, 91 and 111 were rejected under 35 USC §102(e) as being anticipated by U.S. Patent No. 6,371,988 to Pafford et al. New independent claim 135 has been added. For at least the reasons set forth below, claims 72-135 are submitted to be in condition for allowance. Reconsideration and allowance of the subject application is respectfully requested.

Objection to Specification – 35 USC §132

The amendment filed with the U.S. Patent and Trademark Office on December 17, 2004 has been objected to under 35 U.S.C. §132 as introducing new matter into the specification. Specifically, in the previously-filed Response, paragraph 66 was amended to include the following sentence: “Each of dowels 500 are illustrated as having a width less than approximately one-half of the width of the adjacent vertebral body.” The Applicant has submitted that the language added to paragraph 66 is supported by the subject application as originally filed. Specifically, Figure 6 and the corresponding description in paragraph 66 support the added language that the dowels 500 each have a width less than approximately one-half of the width of the adjacent vertebral body. Indeed, Figure 6 illustrates bilateral placement of a pair of spinal implants 500 in a side-by-side manner within the confines of the intervertebral disc space between adjacent vertebral bodies V. Since each of the spinal implants 500 defines a maximum width between the interior facing side 535 and the exterior facing side, and since the spinal implants 500 are positioned entirely within the intervertebral disc space, the maximum width of each of the spinal implants 500 must necessarily be less than approximately one-half of the width of the adjacent vertebral bodies, as recited in independent claims 72, 91 and 111 and as described in paragraph 66 of the subject application.

Nevertheless, the Office Action refers the Applicant to MPEP §2125 and to the case of Hockerson-Halberstadt, Inc. v. Avia Group Int’l for the proposition that drawings can not be

scaled to provide evidence of the actual size or dimensions associated with the features shown in the drawings. The Applicant generally agrees with this proposition. However, the Applicant submits that Figure 6 in the subject application is not being scaled to determine the particular size or dimensions of the spinal implants 500, which was the issue specifically addressed in the Hockerson-Halberstadt decision. (“[I]t is well established that patent drawings . . . may not be relied on to show particular sizes if the specification is completely silent on the issue.” 222 F.3d 951, 956 (Fed. Cir. 2000)). Instead, Figure 6 is being referred to in the context of illustrating the bilateral placement of a pair of spinal implants 500 in a side-by-side manner within the confines of the intervertebral disc space, and that such illustration would clearly convey to one of ordinary skill in the art that such bilateral placement necessarily dictates that the maximum width of each of the spinal implants 500 must be less than approximately one-half of the width of the adjacent vertebral bodies. The Applicant is not, however, relying on Figure 6 to establish measurements which evidence the actual size or dimensions of the spinal implants 500.

Moreover, as also cited in the Office Action, the In re Wright decision stands for the proposition that drawing figures can be relied on “for what they would reasonably teach one of ordinary skill in the art.” 569 F.2d 1124 (CCPA 1977). Indeed, this is precisely what the Applicant is relying on Figure 6 to convey. Specifically, Figure 6 clearly illustrates and paragraph 66 correspondingly describes the bilateral placement of a pair of spinal implants 500 within the confines of the intervertebral disc space, and such disclosure would reasonably convey to one of ordinary skill in the art that the maximum width of each of the spinal implants 500 must necessarily be less than approximately one-half the width of the adjacent vertebral bodies. Moreover, as set forth in MPEP §2163.06, “information contained in any one of the specification, claims, or drawings of the application as filed may be added to other part of the application without introducing new matter.” (Emphasis added). Accordingly, the Applicant submits that it is proper to incorporate description into the specification based on information that the drawings would convey to one of ordinary skill in the art. As a result, the language added to the specification that each of the dowels 500 has a width less than approximately one-half of the width of the adjacent vertebral body (as shown in Figure 6)

does not constitute new subject matter since the as-filed application clearly illustrates this feature of the claimed invention.

For at least the above-discussed reasons, the Applicant submits that the language added to paragraph 66 is properly supported by the subject application as originally-filed. Accordingly, withdrawal of the objection to the specification under 35 USC §132 is respectfully requested.

Claim Rejections – 35 USC §112

Claims 72-134 were rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. Specifically, it has been alleged that the phrase “opposed upper and lower portions between said leading and trailing ends adapted to be placed at least in . . . said upper and lower portions being non-arcuate along at least a portion of the length of the implant”, as recited in each of the independent claims 72, 91 and 111, is not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventors had possession of the claimed invention. The Applicant respectfully disagrees with this rejection for at least the following reasons.

In paragraph 4 of the Office Action, it is stated that “[i]f one were to dissect (sic) the invention in half and look at the side as a whole, there would be a portion that is ‘arcuate’.” The Applicant fails to understand this statement. Although not specifically illustrated in the drawing figures,¹ the specification of the subject application describes other embodiments of implants including implants having a wall including “upper and lower flattened portions . . . achieved by reducing the height H of the sidewall 505 and ends 501, 502” of the implant. (See paragraph 78, lines 1-5). A cross section of such an implant embodiment would clearly show the flattened portions extending along the length of the implant between the ends 501, 502. Thus, Applicant is unclear as to the statement in the Office Action that “there would be a portion that is ‘arcuate’.” The only interpretation that would be consistent with this statement

¹ However, if it would advance prosecution of the subject application, the Applicant will submit one or more additional drawings illustrating the disclosed embodiment of the invention having upper and lower flattened portions.

would be taking a transverse or lateral cross section of the implant with reference given to the curved sides extending between the upper and lower flattened portions. However, while the sides of the implant would be arcuate, the upper and lower flattened portions would clearly not have an arcuate configuration. If the rejection of claims 72-134 under 35 U.S.C. §112 is maintained, the Applicant respectfully requests clarification regarding the statement set forth in the Office Action that “there would be a portion that is ‘arcuate’.”

Furthermore, although the specification does not specifically describe the upper and lower portions as being “non-arcuate”, the Applicant submits that the language recited in the claims need not be described in the specification using precisely the same terminology. Indeed, when claiming an invention, “there is no *in haec verba* requirement”. MPEP §2163, I-B. Instead, “added claim limitation must be supported in the specification through express, implicit, or inherent disclosure.” *Id.* Furthermore, the standard for sufficiency of support is whether the disclosure reasonable conveys to the artisan that the inventors had possession of the subject matter at the time of filing the application. MPEP §2163.02.

With the above-mentioned principles in mind, the Applicant submits that the phrase “said upper and lower portions being non-arcuate”, as recited in independent claims 72, 91, 111 and 134, is sufficiently supported by the phrase “upper and lower flattened portions” set forth in paragraph 78 of the specification. Specifically, the term “flattened” is defined in Webster’s New World Dictionary (3rd College Ed.) as “having little or no depression or elevation”. Additionally, the term “arcuate” is defined as “curved” or “arched”. The term “non-arcuate” would thereby logically be defined as having little or no curvature or arch. As a result, “non-arcuate” falls within the definition of “flattened” in that a feature described as “non-arcuate” would have “little or no depression or elevation”. Therefore, the Applicant submits that the term “flattened” implicitly or inherently supports the term “non-arcuate”. Moreover, the Applicant submits that the standard for sufficiency of support is satisfied in that disclosure of the phrase “upper and lower flattened portions” reasonably convey to a person of ordinary skill in the art that that the inventors had possession of the claimed invention (i.e., an implant with the “upper and lower portions being non-arcuate”) at the time of filing the application based, at least in part, on the disclosure set forth in paragraph 78 of the specification. For at least these reasons, the Applicant respectfully requests withdrawal of the

rejection of independent claims 71, 91, 111 and 134 as failing to comply with the written description requirement of 35 U.S.C. §112, first paragraph.

Finally, paragraph 4 of the Office Action also asserts that recitation of the phrase “less than approximately one-half of the width of the adjacent vertebral bodies” in independent claims 71, 91 and 111 constitutes new matter. The Applicants respectfully disagrees with this assertion for reasons similar to those discussed above with regard to the objection to the specification under 35 U.S.C. §132. Accordingly, the Applicant respectfully requests withdrawal of the rejection of independent claims 71, 91 and 111 as reciting new matter.

Claim Rejections – 35 USC §102

Claims 72, 91 and 111 were rejected under 35 U.S.C. §102(e) as being anticipated by U.S. Patent No. 6,371,988 to Pafford et al. (hereafter “the ‘988 patent”). The Applicant notes that independent claim 134 was not rejected under 35 U.S.C. §102(e).

It is well established that “an invention is anticipated if the same device, including all the claim limitations, is shown in a single prior art reference. Every element of the claimed invention must be literally present, arranged as in the claim.” Richardson v. Suzuki Motor Co. Ltd., 9 USPQ.2d 1913, 1920 (Fed. Cir. 1989).

Paragraph 6 of the Office Actions asserts that the ‘988 patent discloses an implant 40 having opposed upper and lower portions that are non-arcuate along at least a portion of the length of the implant. The non-arcuate upper portion is asserted to constitute the beveled surface (shown in Figures 47 and 48) and the non-arcuate lower portion is asserted to constitute the crest 44 of the tooth 43 (shown in Figure 8). Albeit that the ‘988 patent discloses that “the crest 44 of each tooth 43 is flat” (column 7, line 65), this description appears to be referring to the appearance of the crest 44 in axial cross-section (as shown in Figure 8) wherein the crest 44 may be considered “flat” in a circumferential sense (i.e., in that the crest 44 extending circumferentially about the implant does not have a pointed configuration as is typically the case with bone threads). However, such a “flat” crest 44 extending along the circumference of the implant would not be flattened along the length of the implant. In other words, when viewed from either end of the implant (or via a transverse

cross section), the crest 44 would still have a circular or arcuate configuration. Accordingly, the “flat” crest 44 described in the ‘988 patent specification would not define upper and lower portions that are flat or non-arcuate along the length of the implant.

Moreover, the beveled surface shown in Figures 47 and 48 is referred to in the Office Action as comprising a non-arcuate upper portion. However, the Applicant respectfully disagrees with this assertion in that the beveled surface does not comprise an upper portion of the implant “to contact and support” an adjacent vertebral body, as recited in independent claims 72, 91, 111 and 134. Specifically, the opening or chamber 25 extending through the implant (as shown in Figures 7, 47 and 48) contains an osteogenic composition and opens onto the upper and lower surfaces of the implant to promote bone growth from the endplates of the respective vertebral bodies and into the chamber 25. (See column 7, lines 50-56). Thus, one of ordinary skill in the art would understand that when the implants are positioned in the disc space, the chamber 25 opens onto the upper and lower surfaces of the implant adjacent the respective vertebral bodies. As a result, the portions of the implant that define the openings of the chamber 25 correspond to the “upper and lower portions” of the implant, and do not correspond to the portion of the implant defining the beveled surface. Indeed, the beveled surface is positioned along lateral or side portions of the implant, which would correspond to the interior or exterior facing side of the implant recited in independent claims 72, 91, 111 and 134. Accordingly, even assuming that the beveled surface comprises a non-arcuate portion of the implant, the beveled surface does not comprise an upper or lower portion of the implant.

In addition to the above-discussed reasons, further reasons support the patentability of independent claims 72, 91, 111 and 134 over the ‘988 patent. For example, independent claims 72 and 134 each recite that the implant is manufactured from a bone ring obtained from a major long bone having a medullary canal, with “said interior side of said implant including at least a portion of the medullary canal so that when said implant is placed side by side with another implant having an interior side including at least a portion of a medullary canal a passage is formed”, with the passage adapted to hold bone growth promoting material to permit bone growth through the common passage formed between the implants. (Emphasis added). This configuration is clearly illustrated in Figure 6 of the subject application wherein

the interior facing sides 535 include at least a portion of the medullary canal so as to define facing chambers 530 of the bilaterally positioned implants 500 to form an elongated compartment 540 that can be filled with an osteogenic composition M. (See paragraph 66).

However, as shown in Figure 24 of the '988 patent, although the implants are positioned side-by-side in a bilateral arrangement, the interior facing sides of the implants (i.e., the sides of the implants which face one another) clearly do not include at least a portion of a medullary canal, as recited in independent claims 72 and 134. Instead, the chambers 25 extend through the mid-portion of the implants, and do not intersect the interior facing sides of the implants. Since the interior sides of the implants do not include "at least a portion of the medullary canal", the '988 patent does not disclose each and every feature recited in independent claims 72 and 134. Accordingly, the '988 patent does not anticipate independent claims 72 and 134. Moreover, the chambers 25 extending through the implants illustrated in Figure 24 of the '988 patent do not form a common passage that is adapted to hold bone growth promoting material. To the contrary, the chambers 25 form separate and discrete passages extending through the implants. Accordingly, for at least these reasons, the Applicant respectfully requests withdrawal of the rejection of independent claims 72 and 134 as being anticipated by the '988 patent.

Additionally, independent claims 91 and 111 each recite that the implant is manufactured from a bone composite material with "said interior side of said implant including a recess so that when said implant is placed side by side with another implant having an interior side including a recess a passage is formed", with the passage adapted to hold bone growth promoting material to permit bone growth through the common passage formed between the implants. (Emphasis added). This configuration is also clearly illustrated in Figure 6 of the subject application wherein the interior facing sides 535 of the implants 500 each include a recess, and with the opposing recesses forming a common passage adapted to hold bone growth promoting.

However, as discussed above with regard to independent claims 72 and 134, although the '988 patent discloses implants that are positioned side-by-side in a bilateral arrangement, the interior facing sides of the implants clearly do not include recesses which form a passage to hold bone growth promoting material, as recited in independent claims 91 and 111.

Instead, the chambers 25 extend through the mid-portion of the implants, and do not intersect the interior facing sides of the implants to form a recess. Since the '988 patent does not disclose each and every feature recited in independent claims 91 and 111, the '988 patent does not anticipate independent claims 91 and 111. Accordingly, for at least these reasons, the Applicant respectfully requests withdrawal of the rejection of independent claims 91 and 11 as being anticipated by the '988 patent.

New Independent Claim 135

New independent claim 135 has been added and differs from independent claim 72 in that independent claim 135 recites that the upper and lower portions of the spinal implant are "flattened along at least a portion of the length of said implant". Additionally, independent claim 135 does not recite the language set forth in independent claim 72 regarding "said maximum width of said implant being less than approximately one-half of the width of the adjacent vertebral bodies into which said implant is adapted to be inserted". Furthermore, independent claim 135 is submitted to be patentable over the '988 patent to Pafford et al. for at least the reasons set forth above in support of the patentability of independent claim 72.

CONCLUSION

In view of the foregoing amendments and remarks, it is respectfully submitted that Applicant's application is now in condition for allowance with pending claims 72-135.

Reconsideration of the subject application is respectfully requested. Timely action towards a Notice of Allowability is hereby solicited. The Examiner is encouraged to contact the undersigned by telephone to resolve any outstanding matters concerning the subject application.

Respectfully submitted,

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